K090744

510(k) Summary for the CLARO

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

APR 15 2010

1. General Information

Submitter:	CLRS Technology Corporation 3183 A-1 Airway Ave. Costa Mesa, CA 92626
Contact Person:	Maureen O'Connell O'Connell Regulatory Consultants, Inc. 5 Timber Lane North Reading, MA 01864
Summary Preparation Date:	April 14, 2010

2. Names

Device Name:	CLARO
Regulation Number:	21 CFR 878.4810
Regulation Name:	Laser Instrument, Surgical, Powered
Regulatory Class:	Class II
Product Code:	OLP

3. Predicate Devices

CLARO (K080638)
Zeno Acne Device (K043377)
ThermaClear (K060653)
Tanda (K080591)
Clear-U (K081307)

4. Device Description

The CLARO is a portable handheld intense pulse light (IPL) device powered by a rechargeable battery. The CLARO uses a Xenon flash lamp which delivers pulses of light with a wavelength range from 400-1100 nm at 1msec pulse duration and a fluence of 6 J/cm^2. The spot size of the CLARO is 1cm^2.

5. Substantial Equivalence Discussion

The CLARO which is the subject of this 510(k) is identical in all technological respects to the CLARO that was cleared for prescription home use in K080638. This application is for OTC clearance of the same device. The CLARO treats acne using both heat and light in exactly the same way as the CLARO cleared in K080638.

The OTC indication for use was based on the Zeno, ThermaClear, Tanda and Clear-U predicate devices that are cleared for OTC treatment of mild to moderate inflammatory acne.

In conclusion, the CLARO shares identical technological characteristics with the CLARO cleared in K080638 and indications for use with the Zeno, ThermaClear, Tanda and Clear-U and is therefore substantially equivalent to the other identified predicate devices.

6. Indications for Use

The CLARO is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

7. Performance Data

The CLARO is identical in electrical, mechanical and output characteristics to the already cleared CLARO for prescription use and complies with IEC 60601-1-1 and IEC 60601-1-2.

Revisions made to the labeling for OTC use were tested in three usability studies and two self-selection studies. The performance data supplied in this 510(k) demonstrated that the vast majority of study participants were able to properly self-select themselves using the box labeling and that study participants were able to properly use the device by reading the instructions in the User's Guide without any assistance.

The first self-selection study included 61 subjects. 98.3% of participants were able to properly self-select themselves using the box labeling. Fifty nine of these subjects also participated in the usability study which evauated if subjects were able to correctly use the device by reading the instructions in the User's Guide. Results showed that overall, 86.4% of the study participants were able to properly use the device, and that 97.2% with the labeling submitted for clearance were able to correctly use the device.

The second self-selection and usability study was conducted with 165 subjects which tested changes to the labeling. The study demonstrated that 95% of the

participants could correctly self-select themselves. Different iterations of the labeling were tested regarding correct device operation and 93% of subjects correctly used the CLARO, based on the final revision of the labeling.

A third usability study was conducted to test additional changes to the labeling. Nineteen subjects participated. 100% of participants correctly operated the CLARO with the final version of the User's Guide.

The nonclinical tests demonstrate that the CLARO is as safe, as effective, and performs at least as safety and effectively as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 15 2010

CLRS Technology Corporation
% O'Connell Regulatory Consultants, Inc.
Ms. Maureen O'Connell
5 Timber Lane
North Reading, Massachusetts 01864

Re: K090744
Trade/Device Name: Claro
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OLP
Dated: March 31, 2010
Received: April 01, 2010

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

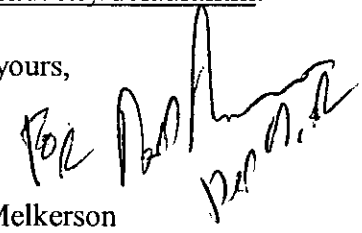
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090744 Pg 1 of 1

Device Name: CLARO

Indications For Use:

The CLARO is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Prescription Use _____ AND/OR Over-The-Counter Use ___X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090744